

Patents & IP Sequences | Clinical Trials | Drug Pipelines

# Medical Devices: Insights from clinical trials, literature, and patents

DPHT Spring Meeting 2016 - Orlando, Florida

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www.bizint.com

## Why Not Drug Pipeline Databases?

Drug Pipeline databases cover drugs:

- "Drug and cell-based products are tracked across all therapeutic areas and throughout the entire development process, from discovery to launch."
- "51,000+ *drug* monographs"
- "over 60,000 highly detailed and fully searchable drug profiles"

A handful of related records in pipeline sources

- Can give the appearance of coverage
- Focus still on the drug drug delivery/formulation/diagnostic

## A device is not a drug

Drug Profile

#### Everolimus

Alternative Names: Absorb; Affinitor; Affinitor Dispersible; Afinitor; Afinitor Disperz; Certican; Esprit BVS; Promus; Promus Element; Promus Premier; RAD; RAD-001; SDZ RAD; Synergy; Votubia; Xience nano: Xience Prime: Xience V

Snapshot

Latest Press Releases

**Development Profile** 

**Development Status** 

Chemical Structures

Sales and Forecasts

Deals and Patents

**SWOT Analysis** 

Change History

Target-based Actions

Sources

Drug Names

Clinical Trials

Literature Review

Xience Xpedition: Zortress everolimus

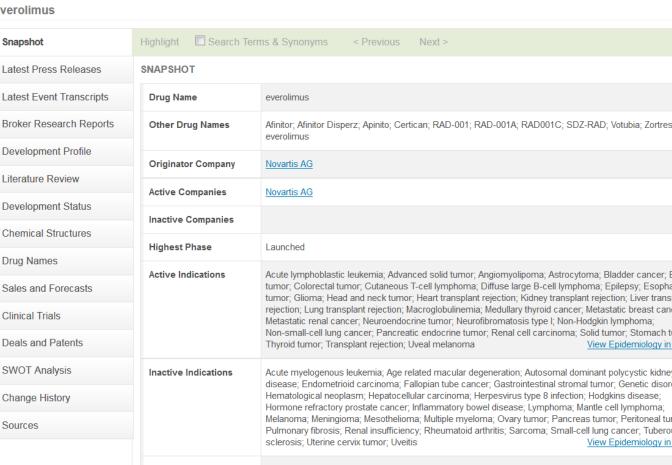
Latest Information Update: 04 Mar 2016 » Print Profile

#### At a glance

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Originator Novartis: Univers Developer Abbott Laborator Boston Scientific Hannover Medica National Cancer Medicine: Novart Collaboration: SC California at San Texas M. D. And Class Antineoplastics;

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mTOR inhibitor; mTOR complex 1 inhibitor

View Epidemiology in

View Epidemiology in

## No Drug Pipeline, No Problem

#### **Clinical Trials**

- What is the mix of trials by phase and status?
- Which companies have clinical stage programs?

#### Literature

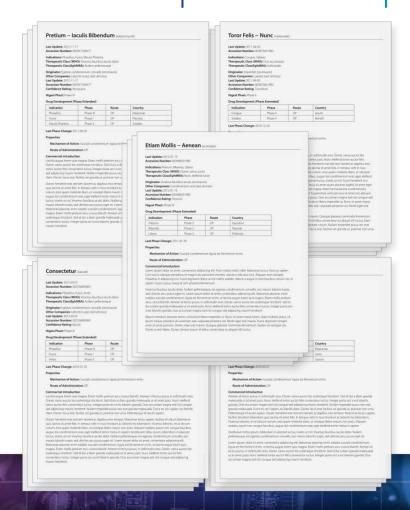
- Who are the key opinion leaders?
- What are the new developments?

#### **Patents**

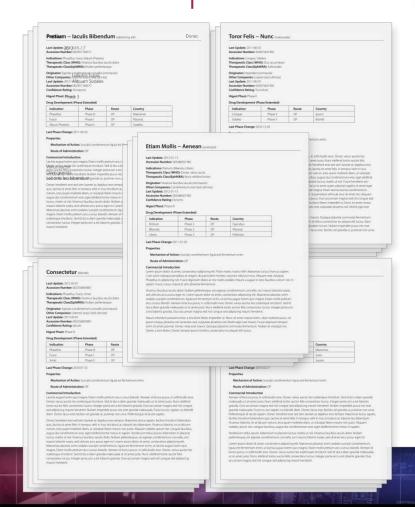
- What are the key companies?
- What novel technologies are they developing?

# BizInt Smart Charts takes your search results

Patents Drug Pipelines Clinical Trials Sequences



## ...and automatically builds summary tables.



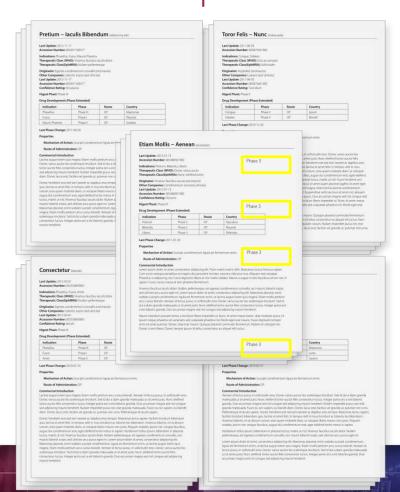
Drug Pipelines | Clinical Trials | Sequences

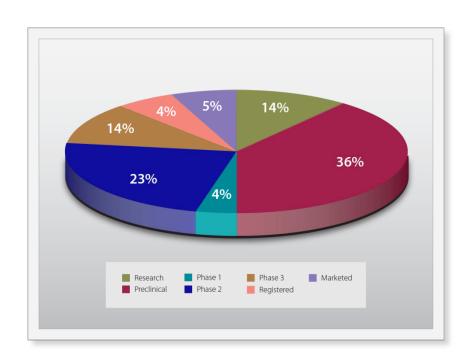
#### Combining results from different databases.

	Drug	Common Drug Name	Database	Synonyms	Highest Phase	Companies	Last Update
1	Siag	Pretium	Database	Synonyma	I I I I I I I I I I I I I I I I I I I	Соправня	Carr opone
2	Pretium XGS	Pretium	Loreet Sem	Varius auctor Diam gravida XS-2	Phase2	Lobortis Turpis Aliquam Sodales	2012-10-01
3	Sollicitudin 4S	Sollicitudin	Donec	Quam diam Augue dui	Phase 3	Egestas Condimetum Lobortis Turpis	2011-12-07
4	Sollicitudin	Sollicitudin	Elifend-UR	Quam diam Augue dui Aenean id lectus	Phase 3	Egestas Condimetum	2011-06-07
5	Etiam Mollis	Etiam Mollis	Loreet Sem	Adiscing Proin Mattis Faucibus lasculus	Phase 3	Condimetum Erat	2012-01-13
6	Etiam Mollis	Etiam Mollis	Elifend-UR	Adiscing Et Sec Proin Mattis Faucibus	Phase 2	Condimetum Erat	2012-01-13
7	Toror Felis	Toror Felis	Donec	Aenead lectus purus Nulla sit amet Quisque placerat 2A	Phase 2	Loareet	2011-06-03
8	Toror Felis III	Toror Felis	Loreet Sem	Aenead lectus purus Quisque placerat	Phase 2	Loareet	2011-06-03
9	Consectetur	Consectetur	Donec	Purus non uma Ligula est Quam sem ac	Phase 3	Lobortis turpis	2012-03-01
0	Consectetur 2A	Consectetur	Nullam	Purus non uma Ligula est	Phase 3	Lobortis turpis	2012-03-01

## And, helps you create visualizations.

# Patents Drug Pipelines Clinical Trials Sequences





## **BizInt Smart Charts**

## Reference Rows™

- Information from related records is displayed in a single "Reference Row".
- Based on database rankings and rules.
- A separate utility working with patent, drug pipeline, clinical trial, and sequence reports.
- Included in all BizInt Smart Charts licenses.

## VantagePoint - Smart Charts Edition

- Clean-up and filter your data.
- Create visualizations to add impact to your reports!
- Custom version of VantagePoint for use with BizInt Smart Charts.
- Add to your BizInt Smart Charts license.
- Sign up for a trial on our web site.



## Topic: Stents, Bioresorbable Stents

Tenekecioglu et al. BMC Cardiovascular Disorders (2016) 16:38 DOI 10.1186/s12872-016-0207-5

**BMC Cardiovascular** 

#### TOMORROW'S MEDICINE

#### REVIEW

#### Bioresorbable scaffolds: a new paradigm in percutaneous coronary intervention

JACC: CARDIOVASCULAR INTERVENTIONS © 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER INC.

http://dx

**EDITORIAL COMMENT** 

#### **Bioresorbable Drug-Eluting Stents**

An Immature Technology in Need of Mature Applica

Robert A. Byrne, MB, BCH, PhD, Adnan Kastrati, MD

ioresorbable coronary stents represent a breakthrough technology promising to enhance the outcomes of patients treated by percutaneous intervention (1). The benefits of bioresorbable stents are intuitive. Indeed, all else being equal, most physicians and patients would agree that a stent that disappears after its useful function is served would be a preferable device to a permanent metallic implant. Moreover, as suggested by recent

ABSORB stent may receive approval f Food and Drug Administration by the

An important requirement for any technology should be demonstration feriority versus contemporary metallic initial phase after implantation (2). This non, an essential condition, for their add as for testing potential late benefit. U

#### New Stent Leaves No Polymer Behind

Boston Scientific's Synergy stent is designed so the drug-elutin breaks down. Are totally bioresorbable stents far behind?

Thomas Morrow, MD

nless you are nearing Medicare age, you will not remember the exhilaration created by the introduction of the News Feature | May 18, 2015

neointimal hyperplas that line the inside of infiltrate the stent th



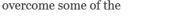


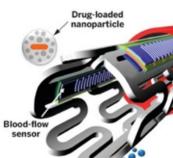


#### Scientists Incorporate Smart Tech **Bioresorbable Stents**

By Suzanne Hodsden

A research team in Korea has developed new innovations for bioresorbable stents by adding a host of biosensors that can track and store data, deliver drugs, and communicate with healthcare providers. This new technology is expected to





## Clinical Trials - challenges for devices

- Not all clinical trial sources cover devices.
- Not all devices require clinical trials.
- Device may not be listed as a Device in ClinicalTrials.gov, but as Procedure, Behavioral, Other.
- Device may be mentioned only in Outcomes or Inclusion/Exclusion Criteria.

#### Which Clinical Trials sources...

#### **Include Medical Devices**

- ClinicalTrials.gov
- Thomson Reuters Cortellis Clinical Trials Intelligence - "includes over 190,000 global trials, covering drugs, biologics, medical devices and biomarkers."
- Adis Clinical Trials Intelligence

#### Which Clinical Trials sources...

#### **Exclude Medical Devices**

- EudraCT "The EU Clinical Trials Register does not: provide information on clinical trials for surgical procedures, medical devices or psychotherapeutic procedures"
- TrialTrove Inclusion/Exclusion per indication. For Coronary Artery Disease, explicitly excluded are "Trials involving drug-eluting stents"

## **Clinical Trials**

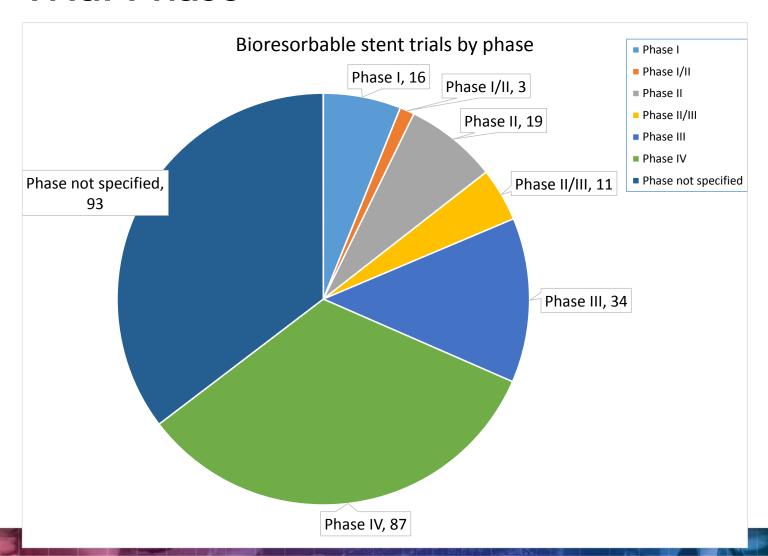
- What is the mix of trials by phase and status?
- Which companies have clinical stage programs?

# Combine and Integrate Trial Records

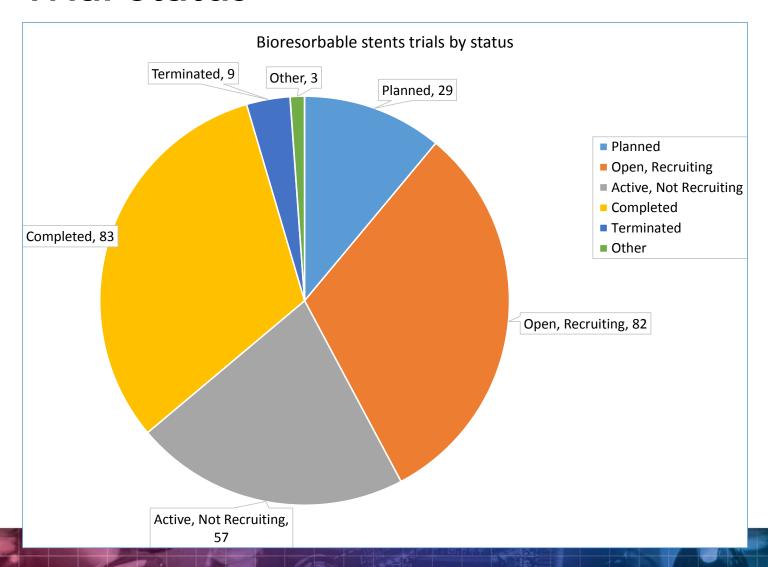
Bioabsorbable Vascular Solutions First in Man Clinical Investigation: A Clinical Evaluation of the Bioabsorbable Vascular Solutions Everolimus Eluting Coronary Stent System (BVS EECSS) in the Treatment of Patients With Single de Novo Native Coronary Artery Lesions	ABSORB A	100.1 NCT   link 100.2 ACT3   link 100.3 CORTT   link	Phase 3	Completed	March 2006	
Investigation: A Clinical Evaluation of the Bioabsorbable Vascular Solutions Everolimus Eluting Coronary Stent System (BVS EECSS) in the Treatment of Patients With Single de Novo Native Coronary Artery Lesions						
Bioabsorbable Vascular Solutions Everolimus Eluting Coronary Stent System (BVS EECSS) in the Treatment of Patients With Single de Novo Native Coronary Artery Lesions		100.3 CORTT   link				
100 1 NCT			3 CORTT   link			
100.11461	100.1 NCT		100.1 NCT	100.1 NCT	100.1 NCT	
Absorb Bioresorbable Scaffold vs. Drug Coated Balloon for Treatment Of In-Stent- Restenosis	AbsorbISR	101.1 NCT   link 101.2 ACT3   link 101.3 CORTT   link	Phase 3	Recruiting	March 2015	
101.1 NCT	101.1 NCT		101.1 NCT	101.1 NCT	101.1 NCT	
BIOTRONIK - A Prospective Randomized Multicenter Study to Assess the SaFety and Effectiveness of the Orsiro SiroLimus Eluting Coronary Stent System in the Treatment Of Subjects With up to Three De Novo or Restenotic Coronary Artery Lesions - V	BIOFLOW-V	102.1 NCT   link 102.2 ACT3   link	Phase 3	Recruiting	May 2015	
102.1 NCT	102.1 NCT		102.1 NCT	102.1 NCT	102.1 NCT	
Performance of Bioresorbable Scaffold in Primary Percutaneous Intervention of ST Elevation Myocardial Infarct (BVS in STEMI)	BVS in STEMI	103.1 NCT   link 103.2 CORTT   link	Phase 3	Recruiting	August 2014	
VTR BRUESSODC PSPS	In the second se	bsorb Bioresorbable Scaffold s. Drug Coated Balloon for reatment Of In-Stent- lestenosis  101.1 NCT  IOTRONIK - A Prospective andomized Multicenter Study of Assess the SaFety and effectiveness of the Orsiro iroLimus Eluting Coronary tent System in the Treatment of Subjects With up to Three e Novo or Restenotic oronary Artery Lesions - V  102.1 NCT  BVS in STEMI Televation Myocardial	bsorb Bioresorbable Scaffold s. Drug Coated Balloon for reatment Of In-Stent-estenosis  101.1 NCT  101.1 NCT  101.1 NCT  101.1 NCT  101.1 NCT  101.1 NCT  IOTRONIK - A Prospective andomized Multicenter Study of Assess the SaFety and affectiveness of the Orsiro iroLimus Eluting Coronary tent System in the Treatment of Subjects With up to Three e Novo or Restenotic oronary Artery Lesions - V  102.1 NCT  102.1 NCT  102.1 NCT  102.1 NCT  102.1 NCT   link  103.1 NCT   link  103.2 CORTT   link  103.2 CORTT   link	bsorb Bioresorbable Scaffold s. Drug Coated Balloon for reatment Of In-Stent-estenosis    101.1 NCT	bsorb Bioresorbable Scaffold s. Drug Coated Balloon for reatment Of In-Stent-estenosis  101.1 NCT  101.1 NCT	



## **Trial Phase**



## **Trial Status**



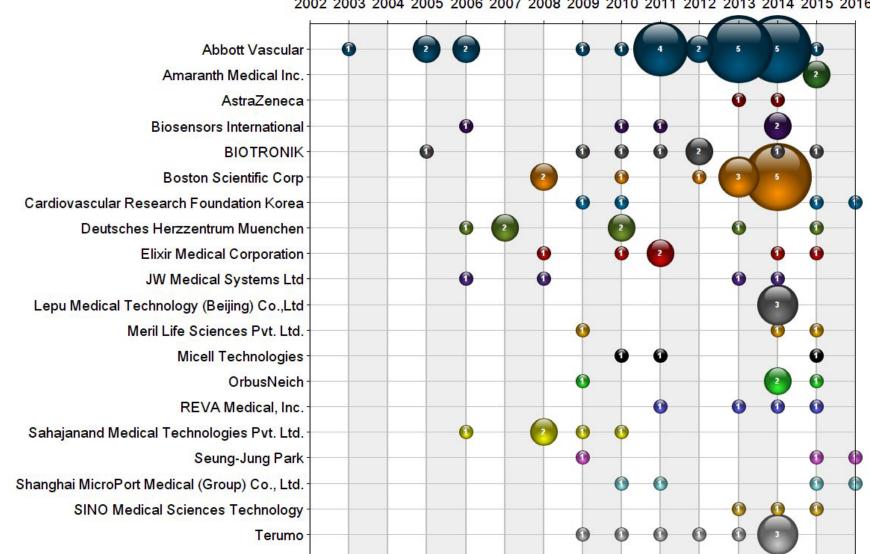
## How do you build it: standard charts

- Clinical Trials -Import and Combine from all sources.
- Reference Rows Integrate to work with data from all sources as a unit.
- VantagePoint Smart Charts Edition (VP-SCE)
  - Normalize phase and status terminology with built-in thesauri.
  - Create charts in VP-SCE or send normalized data to Excel or another charting tool.

## Trial Trends - Company by Trial Start

Bioresorbable stent trials by start date

2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016



## Look for trends - building a bubble chart

- Clinical Trials Import and Combine.
- Reference Rows Integrate to work with data from all sources as a unit.
- VP-SCE
  - Cleanup company names.
    - Use fuzzy matching for faster cleanup.
    - Save cleanup as a thesaurus for future work.
  - Extract start year from trial start date.
  - Create the bubble chart.

## Which Literature sources...

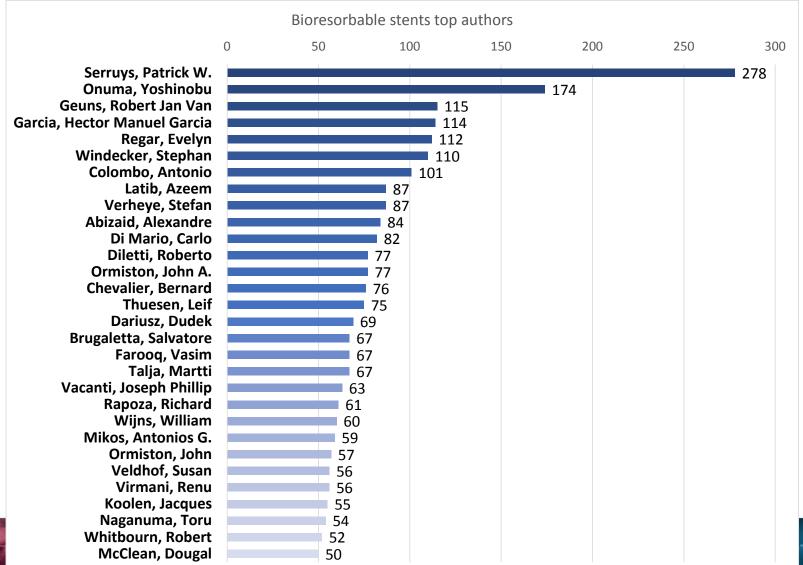
#### Biomedical databases

- MEDLINE®
- Embase®
- BIOSIS Previews®

## Literature

- Who are the key opinion leaders?
- What are the new developments?

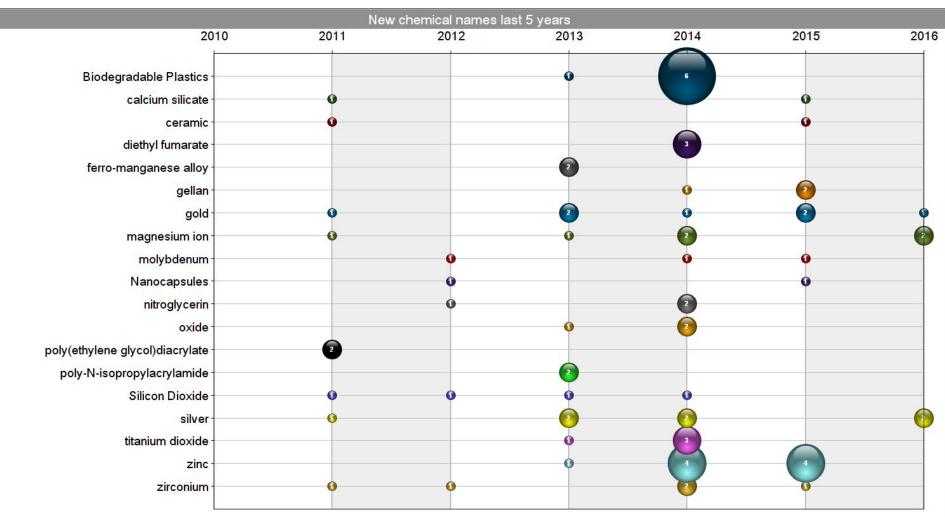
## Look for Key Opinion Leaders



## Steps in building standard charts

- Literature Import and Combine.
- Reference Rows Integrate.
- VantagePoint Smart Charts Edition (VP-SCE)
  - Cleanup author names.
    - Use fuzzy matching for faster cleanup.
    - Save cleanup as a thesaurus for future work.
  - Create charts in VP-SCE or send normalized data to Excel or another charting tool.

## Identify new developments



## Identify what's new

- BizInt Smart Charts Import and Combine.
- VP-SCE
  - Extract year from publication date.
  - Automatically identify terms by first year.
  - Select years to focus on (2011-2016).
  - Create the bubble chart.
  - Review in VP-SCE or export back to BizInt Smart Charts to review the associated literature in more detail.

## Review the associated literature

	Title	Author	Source	Publication Date	Chemical names last 5 yrs
2	Fe-Au and Fe-Ag composites as candidates for biodegradable stent materials	Huang, Tao Cheng, Jian Bian, Dong Zheng, Yufeng	Journal of Biomedical Materials Research - Part B Applied Biomaterials (Feb 1, 2016), vol. 104, no. 2, p. 225-240.	2016-02-01	gold silver
3	Biphasic responses of human vascular smooth muscle cells to magnesium ion	Zhao, Nan Zhu, Donghui	Journal of Biomedical Materials Research - Part A (Feb 1, 2016), vol. 104, no. 2, p. 347-356.	2016-02-01	magnesium ion
4	Strength reliability and in vitro degradation of three-dimensional powder printed strontium-substituted magnesium phosphate scaffolds	Meininger, Susanne Mandal, Sourav Kumar, Alok Groll, Jürgen Basu, Bikramjit Gbureck, Uwe	Acta Biomaterialia (Feb 1, 2016), vol. 31, p. 401-411.	2016-02-01	magnesium ion
5	6-Month Follow-Up of a Novel Biodegradable Drug-Eluting Stent Composed of Poly-L-Lactic Acid and Amorphous Calcium Phosphate Nanoparticles in Porcine Coronary Artery	Xiao, Jianmin Feng, Gaoke Kang, Guanyang Lan, Zhiyuan Liao, Tianshi Kislauskis, Edward Chen, Jiuhao Xia, Jinxi Wang, Zhimin Huo, Zhicheng Wang, Qun Xi, Tingfei McCarthy, Stephen Jiang, Xuejun Wu, Tim Laham, Roger	Journal of biomedical nanotechnology (Oct 2015), vol. 11, no. 10, p. 1819-25.	2015-10-01	Nanocapsules
6	Biodegradable Stent Platforms: Are We Heading in the Right Direction?	Lavi, Shahar Džavík, Vladimír	Canadian Journal of Cardiology (Aug 1, 2015), vol. 31, no. 8, p. 957-959.	2015-08-01	gold
7	Effectiveness of Biodegradable Magnesium Alloy Stents in Coronary Artery and Femoral Artery	Yue, Yunan Wang, Lili Yang, Nuo Huang, Jinglin Lei, Licheng Ye, Huiming	Journal of Interventional Cardiology (Aug 1, 2015), vol. 28, no. 4, p. 358-364.	2015-08-01	aluminum zinc

Yang, Shuixiang

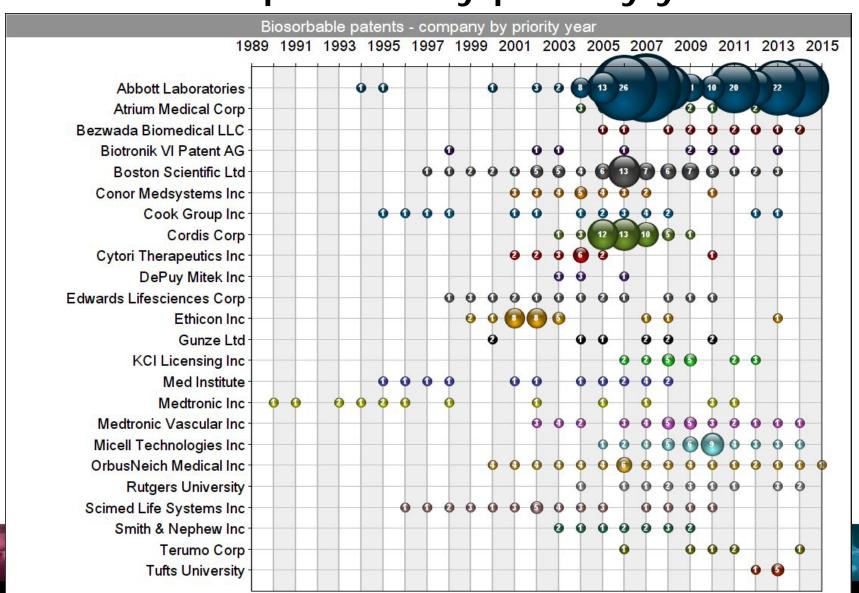
## Which Patent sources...

- Thomson Reuters Cortellis
- PatBase
- LifeQuest

#### **Patents**

- What are the key companies?
- What novel technologies are they developing?

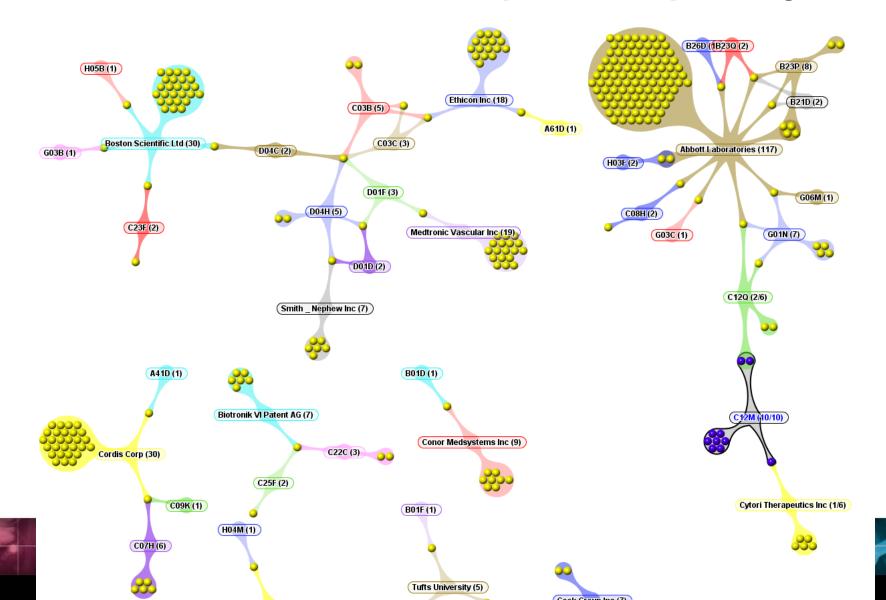
## Trends- competitors by priority year



## Look for trends - building a bubble chart

- Patents Import and Combine from all sources.
- Reference Rows Integrate to work with data from all sources as a unit.
- VP-SCE
  - Cleanup company names.
    - Use fuzzy matching for faster cleanup.
    - Save cleanup as a thesaurus for future work.
  - Extract priority year from priority date.
  - Create the bubble chart.

## Classification codes unique to top assignees



## Differentiate top companies

- Patents Import and Combine from all sources.
- Reference Rows Integrate.
- VP-SCE
  - Cleanup company names.
  - Select top companies to focus on.
  - Automatically identify IPC codes unique to a single top assignee.
  - Create the Aduna cluster map.
  - Review in VP-SCE or export back to BizInt Smart Charts.

## Classification codes unique to top assignees

	Title	Database	Original Assignee	Priority Date	IPCs unique among top assignees
1.	THIN STRUT STENT FROM BIOABSORBABLE POLYMER WITH HIGH FATIGUE AND RADIAL STRENGTH AND METHOD TO MANUFACTURE THEREOF	1.1 Patbase   link	MERIL LIFE SCIENCES PVT LTD	2014-07-07	B21D39
	1.1 Patbase		1.1 Patbase	1.1 Patbase	1.1 Patbase
2.	The short pulse laser machining which is improved using the light absorbing agent for manufacturing the medical device like the stent of the polymer.	2.1 CORTP   link 2.2 Patbase   link	Abbott Cardiovascular Systems Inc.	2013-03-13	B23K35
	2.1 CORTP		2.1 CORTP	2.1 CORTP	2.1 CORTP
3.	Laser cut intraluminal medical devices	3.1 CORTP   link	Cordis Corporation	2005-12-15	B23K6
•		3.2 Patbase   link			
	3.1 CORTP		3.1 CORTP	3.1 CORTP	3.1 CORTP
4.	Micro-structured and nano-structured surfaces on biodegradable polymers	4.1 LIFEQ   link	NANYANG TECHNOLOGICAL UNIVERSITY	2005-07-06	B27N3
	4.1 LIFEQ		4.1 LIFEQ	4.1 LIFEQ	4.1 LIFEQ
5.	BIOMIMETIC SCAFFOLDS	5.1 Patbase   link 5.2 LIFEQ   link	HASHI CRAIG HUANG NGAN FONG KURPINSKI KYLE LI SONG PATEL SHYAM UNIV CALIFORNIA	2006-01-27	B27N3
	5.1 Patbase		5.1 Patbase	5.1 Patbase	5.1 Patbase
6.	Bioabsorbable stent with layers having different degradation rates	6.1 CORTP   link 6.2 Patbase   link	Abbott Cardiovascular Systems Inc.	2008-02-25	B28B11 B29C37
	6.4 CORTR		6.1 CORTR	6.1 CORTE	



# Business Intelligence BizInt Smart Charts

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